

FEB 17 2006

K053318

## Section II

### 510(K) Summary

#### **Company Information:**

Epimed International, Inc.  
141 Sal Landrio Drive  
Johnstown, NY 12095  
(518) 725-0209  
Contact: Christopher B. Lake  
Manager of QA/RA

#### **Date Prepared:**

October 31, 2005

#### **Trade Name:**

RX Epidural Needle

#### **Common Name:**

Epidural Needle

#### **Product Class/Classification:**

Class II  
868.5150 Needle, Conduction, Anesthetic

#### **Predicate Device(s):**

Epimed International Epidural Needle (K030562)

#### **Description:**

The RX Epidural Needle consists of a stainless steel cannula with a ground beveled distal tip. A plastic hub is molded onto the proximal end of the cannula. A stylet is also provided with the device which consists of a custom trimmed shaft and a molded plastic hub.

The RX Epidural Needle will be provided as a sterile, single use, disposable device. The RX Epidural Needle will be available in a variety of lengths and gauges.

**Intended Use:**

The RX Epidural Needle is intended for the epidural placement, directly or through an epidural catheter, of anesthetic agents to elicit regional anesthesia.

**Comparison to Predicate:**

The RX Epidural Needle has similar physical and technical characteristics to the Epimed International Epidural Needle marketed under K030562.

**Conclusion:**

The comparison to the predicate device demonstrates that the RX Epidural Needle is safe and effective and is substantially equivalent to the predicate device.

Epimed International, Inc.



Christopher B. Lake  
Manager of Quality Assurance/Regulatory Affairs



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 17 2006

Mr. Christopher Lake  
Manager of Quality Assurance and Regulatory Affairs  
Epimed International, Inc.  
141 Sal Landrio Dr.  
Crossroads Business Park  
Johnstown, NY 12095

Re: K053318

Trade/Device Name: RX Epidural Needle  
Regulation Number: 868.5150  
Regulation Name: Anesthesia conduction needle  
Regulatory Class: II  
Product Code: BSP  
Dated: November 28, 2005  
Received: December 6, 2005

Dear Mr. Lake:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

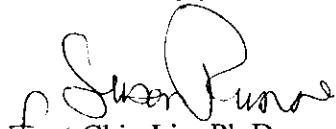
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

  
for Chiu Lin, Ph.D.

Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): unk. **K053318**

Device Name: RX Epidural Needle

Indications For Use:

The RX Epidural Needle is intended for the epidural placement, directly or through an epidural catheter, of anesthetic agents to elicit regional anesthesia.

Prescription Use  \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*George S. Wilson*  
George S. Wilson, M.D.  
Medical Director, Radiology General Hospital,  
Division of Control, Dental Devices  
**K053318**

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